Zypred

Loteprednol Etabonate 0.5% and
Gatifloxacin 0.3%
Ophthalmic Suspension

Composition:
Zypred Ophthalmic Suspension: Each ml contains Loteprednol Etabonate INN 5 mg and Gatifloxacin Sesquihydrate INN equivalent to Gatifloxacin 3 mg.
Preservative: Benzalkonium Chloride Solution BP 0.005%.
Vehicle: Povidone BP 0.6%.
Pharmacology:
Loteprednol (corticosteroids) are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. The antibacterial action of gatifloxacin results from inhibition of DNA gyrase and topoisomerase IV.
Indications:
Zypred is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Ocular steroids are indicated in inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, iritis, cyclitis.
Dosage & Administration:
During the initial 24 to 48 hours, dose may be 1 to 2 drops into the affected eye(s) in every 1 to 2 hours' interval, after that apply in every 4 to 6 hours' interval. Dosing frequency should be decreased gradually upon improvement in clinical signs.
Contra-indications:
Loteprednol Etabonate and Gatifloxacin combination is contraindicated in most viral diseases of the cornea and conjunctiva. It is also contraindicated in known hypersensitivity to any of the ingredients of this preparation.
Adverse reactions:
Reactions associated with ophthalmic steroids include elevated IOP. The most frequently reported adverse effects were conjunctival irritation, increased lacrimation, keratitis, and papillary conjunctivitis. Other reported reactions were chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain, headache, red eye, itching and blurred vision were seen in some cases.
Warnings and Precautions:
If this drug is used for 10 days or longer, intraocular pressure should be monitored. If redness or itching becomes aggravated, the patient should be advised to consult a physician. Patients who wear soft contact lenses and whose eyes are not red, should be instructed to wait at least ten minutes after instilling it before they insert their contact lenses.
Use in Special group:
Pregnancy: *Pregnancy Category C.* There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers: Caution should be exercised when **Zypred** Ophthalmic Suspension is administered to a nursing woman.
Pediatric Use: Safety and efficacy in pediatric patients have not been established.
Geriatric use: Safety and efficacy in geriatric patients have not been established.
Storage:
- Store below 30°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:
Zypred Ophthalmic Suspension: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

ARISTOVISION

Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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